10D

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,674	03/09/2001	Roberto A. Macina	DEX-0142	9969

7590 04/01/2004

Licata & Tyrrell P.C.
66 E. Main Street
Marlton, NJ 08053

EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/802,674	MACINA ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment and Argument

1. Claim 1 is pending.

Claim 1 has been amended.

Claim 1 is examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

Claim Rejections - 35 USC § 103

3. The rejection of claim 1 under 35 U.S.C. 103(a) as being unpatentable over US Patent Application Publication number 2003/0109690 A1 (June 12, 2003) is withdrawn in light of the claim amendment.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

4. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for detecting the presence of gastrointestinal cancer in a patient comprising determining levels of SEQ ID NO: 3 in cells, tissue or bodily fluids in a patient and comparing the determined levels of SEQ ID NO: 3 in cells, tissue or bodily fluids from a normal human control, wherein at least a two-fold decrease in determined levels of SEQ ID NO: 3 in said patient versus normal human control is associated with presence of gastrointestinal cancer, does not reasonably provide enablement for a method for detecting the presence of gastrointestinal cancer in a patient comprising determining levels of a polynucleotide encoding a polypeptide comprising SEQ ID NO: 4.

Applicants have asserted that SEQ ID NO: 3, a polynucleotide sequence can be implemented in a molecular based diagnostic method for detection of a gastrointestinal cancer, see January 21, 2003. However, Applicants have not provided any disclosure enabling the use of polynucleotides encoding a polypeptide of SEQ ID NO: 4 in a method for detecting the presence of gastrointestinal cancer in a patient. There is insufficient evidence presented in the specification providing the definitive applicability of variant and degenerate polynucleotides of SEQ ID NO: 3, as well as arbitrary polynucleotides that encode SEQ ID NO: 4 in the claimed method. There is no disclosure designating what changes could be made with the polynucleotide sequence of SEQ ID NO: 3 and the consequent use of the resulting altered polynucleotides in the

claimed method. The experimental design presented in the specification lacks information regarding the applicability of degenerate equivalent sequences in diagnostic methods relative to gastrointestinal cancer and that they would also be decreased at least two-fold in patient samples. It is not reasonable to conclude that degenerate polynucleotide sequences that may encode SEQ ID NO:4 would be effective in yielding a discriminate diagnosis of any gastrointestinal cancer.

Based on the analysis and the teachings presented above the claims do not read on the entire breadth of the claim. There is insufficient support in the specification for the enablement of the broadly claimed invention.

5. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is broadly drawn to a method for detecting the presence of gastrointestinal cancer in a patient comprising determining levels of SEQ ID NO: 3 or *a polynucleotide encoding a polypeptide comprising SEQ ID NO: 4* in cells, tissue or bodily fluids in a patient and comparing the determined levels of SEQ ID NO: 3 or *a polynucleotide encoding a polypeptide comprising SEQ ID NO: 4* with levels of SEQ ID NO: 3 or *a polynucleotide encoding a polypeptide comprising SEQ ID NO: 4* in cells, tissue or bodily fluids from a normal human control, wherein at least a two-fold decrease

in determined levels of SEQ ID NO: 3 in said patient versus normal human control is associated with presence of gastrointestinal cancer.

The phrase, "a polynucleotide encoding a polypeptide comprising SEQ ID NO: 4" in the claimed method encompasses allelic variants, analogs, homologs and degenerate polynucleotide sequences of SEQ ID NO: 3. The written description in this instant case only sets forth the nucleic acid, SEQ ID NO: 3 that encodes the polypeptide designated as SEQ ID NO: 4. The written description is not commensurate in scope with the claims that embody polynucleotides other than SEQ ID NO: 3.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

With the exception of nucleic acid, SEQ ID NO: 3 and the encoded polypeptide SEQ ID NO:4, the skilled artisan cannot envision all the nucleic acids and the detailed structure of the encompassed polypeptides that are applicable to the claimed method and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a

reference to a potential method of isolating it. The polynucleotide itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

At the time the application was filed Applicants only had possession of SEQ ID NO: 3 and 4 and not nucleotides and polypeptides that share less than 100% sequence identity with SEQ ID NO:3 and 4, respectively. The specification does not evidence the possession of all the degenerate polynucleotides of SEQ ID NO: 3 that may or may not encode SEQ ID NO: 4 capable of exhibiting at least a two-fold decrease. There is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

The full breadth of the claims do not meet the written description provision of 35 U.S.C. 112, first paragraph.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however can normally be reached between the hours of 7:00 am to 4:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne "Bonnie" Eyler, Ph.D. can be reached on (571)272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alana M. Harris, Ph.D.
23 March 2004
ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER